REMARKS

Election/Restrictions

Claims 23, 26, 27 and 50-60 have been withdrawn from consideration as being drawn to a non-elected invention and species of the invention. The Applicant has chosen to maintain the withdrawn claims 23, 26 and 27 in the pending application for possible reinstatement upon the allowance of one or more generic base claims. The Applicant has cancelled claims 50-60 without prejudice for possible submission in a continuing application.

Claim Rejections – 35 USC §102 and §103

Claims 1-18, 21, 22, 28-35 and 37-49 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0040243 to Attali et al. (hereafter "the Attali reference"). Additionally, claims 19, 20, 24, 25 and 36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Attali reference in view of U.S. Patent Application Publication No. 2002/0045945 to Liu et al. (hereafter "the Liu reference"). "[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Independent Claims 1 and 49 and Dependent Claims 2-29

As indicated above, independent claims 1 and 49 have been rejected as being anticipated by the Attali reference. In order to more clearly define the present invention, independent claims 1 and 49 have each been amended to recite a body having a longitudinal axis, an overall length and an overall width and including a plurality of movable portions "cooperating to define a <u>non-threaded</u> outer <u>transverse</u> cross section <u>along said overall length</u>", with the movable portions defining first and second substantially planar outer surfaces disposed generally opposite one another and "extending substantially entirely across said overall width".

With regard to the Attali reference, each of the implant embodiments, including the implant embodiment illustrated in Figures 3-5, are externally threaded along over one-half of the

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overall length L of the cage body 1. Specifically, the Attali reference indicates that "[w]hatever the embodiment, at least a portion of the outside surface of said branches 5 is threaded with a thread profile 11 having projecting ridges, as shown in detail in FIG. 7. In particular, by way of example, for a cage having a length L of about 20 mm to 25 mm, the length 1 of the threaded portion of the branches 5 may lie in the range 13 mm to 16 mm Such an outside thread with projecting ridges thus facilitates installation since it is not traumatizing, given that there is no impact shock while inserting said implant since it is screwed into a hole previously bored by any tool compatible with the orifice 8 of the implant, and once in place such a thread also provides anchoring in the bone, thereby avoiding any subsequent migration." (¶¶ 32-33; emphasis added).

Accordingly, the implant embodiments disclosed in the Attali reference do not include a plurality of movable portions "cooperating to define a non-threaded outer transverse cross section" along the overall length of the implant. Additionally, as disclosed in the subject application, providing the implant body with a non-threaded outer transverse cross section provides various advantages over threaded implant designs. Specifically, as disclosed in the subject application, "since the spinal implant 20 is not externally threaded, forming a cylindrically-shaped passage between and into the adjacent vertebrae V_U, V_L and tapping the passage is not required. Accordingly, removal or disruption of vertebral tissue from the upper and lower vertebrae V_U, V_L is minimized." Additionally, "since the spinal implant 20 is not threaded, insertion into the disc space can be accomplished without having to thread or otherwise rotate the spinal implant 20 into position." (Page 22, line 15 to page 23, line 3).

Moreover, as illustrated in Figures 3-5 of the Attali reference, even assuming arguendo that portions of the upper and lower surfaces of the cage 1 that are engaged with the upper and lower vertebrae are substantially planar, the planar portions do not extend substantially entirely across the overall width of the cage 1, as recited in independent claims 1 and 49. Instead, the planar portions of the upper and lower surfaces only extend across approximately two-thirds of the overall width of the implant (see Figures 4A and 5A), with the remainder of the implant width being defined by the arcuate thread segments disposed on either side of the planar upper and lower portions. As discussed above, each of the implant embodiments disclosed in the Attali reference is externally threaded. Since each of the branches 5 are provided with external threads,

the upper and lower portions of the cage body 1 do not define planar surfaces extending across the overall width of the implant. Additionally, if the cage body 1 were to somehow include first and second planar surfaces extending across the overall width of the implant, rotational threaded insertion of the cage body 1 into the intervertebral space would be greatly impeded if not prevented, and the risk of trauma to the implant site would be greatly increased.

Accordingly, the implant embodiments disclosed in the Attali reference do not include a plurality of movable portions defining first and second substantially planar outer surfaces extending substantially entirely across an overall width of the cage body 1, as recited independent claims 1 and 49. Additionally, the Applicant submits that providing the implant recited in independent claims 1 and 49 with planar outer surfaces extending substantially entirely across an overall width of the implant in turn provides an enlarged exterior surface area for engagement with the adjacent vertebrae, thereby leading to increased implant stability and support of the adjacent vertebrae, as well as an increased surface area in contact with the adjacent vertebrae which provides increased opportunity for bone tissue growth onto the implant body and into the interior chamber, all of which are desirable features that are neither taught nor suggested by the Attali reference.

For at least the reasons set forth above, the Applicant submits that independent claims 1 and 49, as amended, are not anticipated by the Attali reference. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 49 and allowance of the same.

Additionally, claims 2-29 depend from independent claim 1 and are patentable for at least the reasons supporting the patentability of independent base claim 1. Moreover, further reasons support the patentability of the claims depending from independent claim 1. For example, claim 2 recites that the movable portions "cooperate to define third and forth substantially planar surfaces disposed generally opposite one another and extending between said first and second substantially planar surfaces". Even assuming arguendo that portions of the upper and lower surfaces of the Attali implant are substantially planar and that portions of the side surfaces are also substantially planar, the planar side portions do not extend between the planar upper and lower portions. Instead, the arcuate thread segments are disposed between the planar side

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portions and the planar upper and lower portions. Accordingly, the planar side portions do not <u>extend between</u> the planar upper and lower portions. Additionally, claim 3 recites that the movable portions cooperate to define "a generally rectangular outer transverse cross section along said overall length". The Applicant submits that the inclusion of the rounded or arcuate thread segments provides the Attali implant illustrated in Figures 4A and 5A with a "cylindrical or quasi-cylindrical" outer cross section having an oval or ovoid shape (¶¶ 10 and 30), and not a generally rectangular outer transverse cross section, as recited in claim 3.

Claim 12 recites that "said inner surfaces of said movable portions provide said inner chamber with a substantially rectangular cross section." However, the Attali reference fails to disclose this claim element. Instead, the inner volume 9 of the cage 1 includes a circular or cylindrical cross section defined by rounded or arcuate internal corners formed along the branches 5.

Claim 18 has been amended to further recite that "said first and second substantially planar surfaces each define a plurality of apertures extending therethrough in communication with said inner fusion chamber to facilitate bone growth from the adjacent vertebral bodies and into the fusion chamber." On page 3 of the Office Action, the slots 10 formed between the branches 5 of the Attali implant are asserted to comprise apertures defined by planar surface of the cage 1. However, the Applicant submits that the slots 10 do not extend through planar surfaces of the cage 1. Instead, the slots 10 are defined between adjacent ones of the moveable branches 5, and do not extend through planar surfaces of the cage 1. Nevertheless, the Applicant has amended claim 18 to recite that each of the first and second substantially planar surfaces define a plurality of apertures extending therethrough in communication with the inner fusion chamber. Even assuming arguendo that the upper and lower slots 10 formed between adjacent branches 5 comprise apertures, each of the upper and lower surfaces of the cage 1 do not define a plurality of apertures extending therethrough in communication with the interior volume 9 of the cage 1. To the contrary, a single slot 10 is formed between adjacent branches 5 along the upper and lower portion of the cage 1. Moreover, it would not have been obvious to modify the slot 10 to define multiple apertures since the slots 10 must extend along the length of the cage 1 in an uninterrupted manner to allow the cage 1 to outwardly expand. Indeed, it the slots 10 were

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divided into multiple axial portions, the branches 5 would not be capable of being displaced away from one another to expand the cage 1.

Independent Claim 30 and Dependent Claims 31-39

Independent claim 30 has been rejected as being anticipated by the Attali reference. In order to more clearly define the present invention, independent claim 30 has been amended to recite a body having a longitudinal axis and an overall length, with the body including a plurality of movable portions "cooperating to define a generally rectangular, non-threaded outer transverse cross section along said overall length".

As discussed above with regard to independent claims 1 and 49, each of the implant embodiments disclosed in the Attali reference, including the implant embodiment illustrated in Figures 3-5, are externally threaded along over one-half of the overall length L of the cage body. Accordingly, the implant embodiments disclosed in the Attali reference do not include a plurality of movable portions "cooperating to define a generally rectangular, non-threaded outer transverse cross section" along the overall length of the implant. Additionally, as also discussed above with regard to independent claims 1 and 49, providing the implant body with a non-threaded outer transverse cross section provides various advantages over threaded implant designs (e.g., avoiding the formation of a cylindrically-shaped passage between the adjacent vertebrae and tapping of the passage, minimizing the removal or disruption of vertebral tissue, insertion of the implant into the disc space without having to thread or otherwise rotate the spinal implant into position).

Additionally, as illustrated in Figures 3-5 of the Attali reference, even though portions of the upper and lower surfaces and side surfaces of the Attali implant appear to be planar, arcuate thread segments are disposed between the planar side portions and the planar upper and lower portions. Accordingly, the branches 5 do not cooperate to define "a generally rectangular" outer transverse cross section along the overall length of the implant. Instead, the inclusion of the rounded or arcuate thread segments provide the Attali implant illustrated in Figures 4A and 5A with a "cylindrical or quasi-cylindrical" outer cross section having an oval or ovoid shape (¶¶ 10 and 30), and not a generally rectangular outer transverse cross section, as recited in independent

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claim 30. Indeed, as discussed above with regard to independent claims 1 and 49, the planar portions of the upper and lower surfaces only extend across approximately two-thirds of the overall width of the implant (see Figures 4A and 5A), with the remainder of the implant width defined by the arcuate thread segments which are disposed on either side of the planar upper and lower portions. Similarly, the planar portions of the side surfaces only extend across approximately two-thirds of the overall height of the implant (see Figures 4A and 5A), with the remainder of the implant height defined by the arcuate thread segments which are disposed on either side of the planar side portions.

Due to the inclusion of the arcuate thread segments extending along a length of each of the branches 5, it can not fairly be said that the branches 5 cooperate with one another to define a generally rectangular outer transverse cross section along the overall length of the implant, as recited in independent claim 30. Additionally, the Applicant submits that providing the implant recited in independent claim 30 with a generally rectangular outer transverse cross section in turn provides an enlarged exterior surface area for engagement with the adjacent vertebrae, thereby leading to increased implant stability and support of the adjacent vertebrae, as well as an increased surface area in contact with the adjacent vertebrae which provides increased opportunity for bone tissue growth onto the implant body and into the interior chamber, all of which are desirable features that are neither taught nor suggested by the Attali reference.

Furthermore, if the Attali implant were provided with a generally rectangular outer transverse cross section, rotational threaded insertion of the cage body 1 into the intervertebral space would be greatly impeded if not prevented, and the risk of trauma to the implant site would be greatly increased.

For at least the reasons set forth above, the Applicant submits that independent claim 30, as amended, is not anticipated by the Attali reference. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 30 and allowance of the same.

Additionally, claims 31-39 depend from independent claim 30 and are patentable for at least the reasons supporting the patentability of independent base claim 30. Moreover, further reasons support the patentability of the claims depending from independent claim 30. For example, dependent claim 37 has been amended to recite that the implant body has an overall

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width, with the movable portions defining first and second substantially planar surfaces "extending substantially entirely across said overall width and adapted to engage adjacent vertebral bodies". As discussed above with regard to independent claims 1 and 49, such features are neither disclosed nor suggested by the implant embodiments of the Attali reference.

Independent Claim 40 and Dependent Claims 41-48

Independent claim 40 has been rejected as being anticipated by the Attali reference. In order to more clearly define the present invention, independent claim 40 has been amended to recite a body having a longitudinal axis and an overall length, with the body including a plurality of movable portions having substantially planar inner surfaces that cooperate to define an inner chamber having "a substantially rectangular inner transverse cross section along said overall length", and with the expansion member having a substantially rectangular outer transverse cross section and "including outer substantially planar surfaces that engage said substantially planar inner surfaces of said movable portions" to expand the movable portions along each of the first and second transverse dimensions.

With regard to the Attali reference, as illustrated in Figures 4A, 5A, 4B and 5B, the inner surfaces of the branches 5 are concavely rounded to define arcuate internal corners which are engaged by the circular outer surface of the spacer 2, thereby providing the inner volume 9 of the cage 1 with a circular inner transverse cross section along the length of the implant, and not a substantially rectangular inner transverse cross section, as recited in independent claim 40. Additionally, the inner arcuate surfaces of the branches 5 which are engaged by the circular outer surface of the spacer 2 are clearly not substantially planar, as recited independent claim 40, but are instead arcuate. Likewise, the spacer illustrated most clearly in Figures 12-14 does not define "a substantially rectangular outer transverse cross section", nor does the spacer include "substantially planar outer surfaces", as recited in independent claim 40. Albeit that an axial cross section taken along the spacer may be rectangular, a transverse cross section taken through the spacer would clearly have a circular configuration. Moreover, the spacer does not include outer substantially planar surfaces that engage substantially planar inner surfaces of the branches 5. Instead, the spacer defines a non-planar, circular outer surface.

Response to non-final Office Action Application Serial No. 10/718,770 Inventors: Charles L. Branch, Jr. Filing Date: November 21, 2003 Additionally, the Applicant submits that providing the implant recited in independent claim 40 with an inner chamber having a substantially rectangular inner transverse cross section allows for a greater amount of a bone growth promoting substance to be positioned within the inner chamber compared to that which may be positioned within an inner chamber having a circular transverse cross section. Additionally, providing the expansion member with a substantially rectangular outer transverse cross section and substantially planar outer surfaces which engage substantially planar inner surfaces defined by the movable portions provides for more secure engagement between the expansion member and the movable portions, thereby leading to increased implant stability during expansion.

For at least the reasons set forth above, the Applicant submits that independent claim 40, as amended, is not anticipated by the Attali reference. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 40 and allowance of the same.

Additionally, claims 41-48 depend from independent claim 40 and are patentable for at least the reasons supporting the patentability of independent base claim 40. Moreover, further reasons support the patentability of the claims depending from independent claim 40. For example, dependent claim 41 has been amended to recite that the body has an overall width, with the movable portions cooperating to define "a non-threaded outer transverse cross section along said overall length" and first and second substantially planar outer surfaces "extending substantially entirely across said overall width". As discussed above with regard to independent claims 1 and 49, such features are neither disclosed nor suggested by the implant embodiments of the Attali reference.

Additionally, claim 43 has been amended to further recite that "each of said first and second substantially planar outer surfaces define a plurality of apertures extending therethrough in communication with said inner chamber." As discussed above with regard to claim 18, the Applicant submits that the slots 10 defined by the Attali implant do not extend through planar surfaces of the cage 1. Instead, the slots 10 are defined between adjacent ones of the moveable branches 5, and do not extend through planar surfaces of the cage 1. Nevertheless, the Applicant has amended claim 43 to recite that <u>each</u> of the first and second substantially planar surfaces define a plurality of apertures extending therethrough in communication with the inner fusion

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chamber. Even assuming arguendo that the upper and lower slots 10 formed between adjacent branches 5 comprise apertures, each of the upper and lower surfaces of the cage 1 do not define a plurality of apertures extending therethrough in communication with the interior volume 9 of the cage 1. To the contrary, a single slot 10 is formed between adjacent branches 5 along the upper and lower portion of the cage 1. Moreover, it would not have been obvious to modify the slot 10 to define multiple apertures since the slots 10 must extend along the length of the cage 1 in an uninterrupted manner to allow the cage 1 to outwardly expand. Indeed, it the slots 10 were divided into multiple axial portions, the branches 5 would not be capable of being displaced away from one another to expand the cage 1.

Furthermore, claim 45 has been amended to recite that the movable portions "cooperate to define a generally rectangular, non-threaded outer transverse cross section along said overall length." As discussed above with regard to independent claim 30, such features are neither disclosed nor suggested by the implant embodiments of the Attali reference.

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CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 1-49.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

 $\mathsf{By}:_{oldsymbol{oldsymbol{oldsymbol{oldsymbol{\mathsf{B}}}}}$

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